REMARKS/ARGUMENTS

Independent claims 48 and 42 remain unamended. New dependent claims 53-57 are identical to previous claims 43-47 that had not been entered when last presented. Similarly, new dependent claims 58-62 are identical to previously presented claims 48-52 which also were not entered when first presented. Entry and examination of the subject matter of those claims is proper at this time.

Reconsideration is requested of the rejection of claims 38 and 42 as anticipated under 35 USC 102 (e) by Berenstein Patent 6,458,119. Berenstein does not disclose applicant's invention for the reasons discussed below.

Applicant's Invention

Applicant's invention is directed to a tissue implant that induces angiogenesis (growth of new blood vessels) in the tissue in which it is implanted while also applying a therapeutic material. The implant is in the form of a scaffold-like structure that can be imbedded within tissue and retained within the tissue by reason of its geometry. The scaffold also is configured to mechanically trigger an injury response in the tissue that leads to angiogenesis in that tissue. The claimed invention also includes thrombus that is associated with the implant to enhance the angiogenesis effect and, further, the thrombus serves as a host matrix for another, therapeutic, material. Claim 38 calls for the thrombus being disposed around the exterior of the device. Claim 42 calls for the therapeutic material comprising an inhibitor adapted to inhibit tumor growth.

Prior Art – U. S. Patent 6,458,119 (Berenstein)

The Berenstein 119 Patent describes a vaso-occlusive device, that is, a device intended to be placed within the flow passage of a blood vessel for the purpose of obstructing the blood vessel and preventing blood flow downstream of the device. The function of such vaso-occlusive devices is well known and is referred to in Berenstein as including ...control of internal bleeding, occlusion of blood supply to tumors, and relief of vessel wall pressure in the region of aneurysm." (1:50-53). Such devices are described in Berenstein as having included polymeric agents introduced into the vasculature through a catheter to form a solid space-filling mass. (1:56-63). Other devices include micro balloons deployed within the lumen of a selected

blood vessel or wire coils or braids introducible into the vessel lumen through a catheter. Berenstein relates to such embolism-forming filaments (coiled, braided, or chains) with very small diameters (less than about 0.010 inches) that are placeable in the lumen of the blood vessel by fluid delivery through a catheter. The Berenstein vaso-occlusive devices are in a long, thin thread-like form having little rigidity or column strength (3:15-18). The device is introduced, through a catheter, into the bloodstream at a selected vascular site where it "...quickly compacts into a significantly denser mass" that serves to occlude the blood vessel. It is said that the device may be coated with thrombotic or therapeutic materials or used in conjunction with fibrous embolic additions. (3:45-48). Because of the flexibility and lack of column strength of the devices, they are extremely soft and flexible and "...exert little if any radial force on the blood vessels into which they are placed." (7:37-41).

Claim Rejections-35 USC Section 102

Reconsideration is requested of each of claims 38 and 42 as anticipated by Berenstein. Berenstein neither discloses nor suggests applicant's claimed invention. "To anticipate, every element and limitation of the claimed invention must be found in a single prior art reference arranged as in the claim." *Brown v 3M*, 265 Fed. 1349, 1341, 60 USPQ 2nd. 1375 (Fed. Cir. 2001).

Berenstein fails to disclose a number of features of applicant's invention. In particular, Berenstein fails to disclose:

- an implant for treating viable tissue
- a scaffold structure that is implantable and retained within the tissue
- a scaffold configured to mechanically trigger an injury response leading to angiogenesis in the tissue
- thrombus associated with the implant and serving as a host matrix for therapeutic material loaded in the thrombus.

Berenstein relates merely to a thin thread-like device to plug the lumen of a blood vessel. It is not implantable within tissue. The purpose for such devices is to prevent downstream blood flow that otherwise could cause injury, such as vascular rupture of a downstream aneurysm or

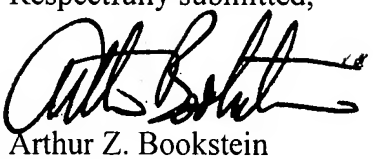
preventing other internal bleeding or might permit further growth of a tumor. Berenstein is unrelated to and does not disclose a device adapted for or capable of being implanted and retained within tissue (as distinguished from being placed within a natural passage way such as a blood vessel lumen) while also having sufficient structural characteristics (e.g. strength and rigidity) to mechanically trigger an injury response in the tissue to an extent that leads to angiogenesis. Indeed, one of the objectives of Berenstein is to provide a device that is "...extremely soft and flexible..." and "...[exerts] little if any radial force on the blood vessels into which they are placed." They are sufficiently flexible and small that they may be carried by the blood flow in the blood vessel. (7:37-46). Where Berenstein fails to disclose a device adapted for or capable of being implanted into tissue or a device with sufficient structure to cause an injury response leading to angiogenesis, it cannot be considered as anticipating either of claims 38 or 42.

Additionally, each of claims 38 and 42 includes the further limitation of thrombus that is loaded with therapeutic material whereby the thrombus provides a host matrix for the therapeutic material. Berenstein merely summarizes that the vaso-occlusive device may be coated with "thrombotic or therapeutic materials" (1:45-47). It does not disclose a scaffold as claimed by applicant in which thrombus is associated with the scaffold and with the thrombus serving as a host matrix for therapeutic materials. Additionally, as Claim 42, there is no disclosure of a therapeutic material comprising a tumor growth inhibitor. The only reference to tumors is connection with occlusion the blood supply to tumors. (1:53).

Claims 53-62 depend from either claims 38 and 42 and are not anticipated by Berenstein for the same reasons. Additionally, these claims include further limitations by which they may be distinguished from Berenstein such as the limitation of an angiogenic substance associated with the scaffold (claims 53 and 58), the therapeutic comprising one of cells, tissue, pre-cursor cells, stem cells, cardio myocites, skeletal myoblasts and growth factors (Claim 54), the scaffold comprising a pellet (claims 55 and 62), the scaffold comprising an open cell foam structure (claims 56 and 60).

The rejection should be withdrawn.

Respectfully submitted,



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